

## PATENT COOPERATION TREATY

REC'D 15 MAR 2006

## PCT



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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference M3153-PCT	<b>FOR FURTHER ACTION</b> See Form PCT/IPEA/416	
International application No. PCT/EP2004/013435	International filing date (day/month/year) 26.11.2004	Priority date (day/month/year) 01.12.2003
International Patent Classification (IPC) or national classification and IPC INV. A61C8/00		
Applicant MATERIALISE N.V. ET AL.		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 10 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 5 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand  20.07.2005	Date of completion of this report  16.03.2006	
Name and mailing address of the International preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized officer  Chabus, H  Telephone No. +31 70 340-2684 

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/EP2004/013435

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-18 as originally filed

**Claims, Numbers**

1-29 filed with telefax on 27.02.2006

**Drawings, Sheets**

1/5-5/5 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/EP2004/013435

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,  
☒ claims Nos. 14-17, 22, 23, 28, 29

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the said claims Nos. 14-17, 22, 23, 28, 29
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- |                            |  |
|----------------------------|--|
| the written form           | <input type="checkbox"/> has not been furnished            |
|                            | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished            |
|                            | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/EP2004/013435

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**Box No. IV Lack of unity of invention**

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1. ☒ In response to the invitation to restrict or pay additional fees, the applicant has:
- ☐ restricted the claims.
  - ☐ paid additional fees.
  - ☐ paid additional fees under protest.
  - ☒ neither restricted nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
  - ☒ not complied with for the following reasons:  
**see separate sheet**
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
  - ☒ the parts relating to claims Nos. 1-13, 18-21, 24-27 .

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	1-13, 19, 21
	No: Claims	18, 20, 24-27
Inventive step (IS)	Yes: Claims	
	No: Claims	1-13, 18-21, 24-27
Industrial applicability (IA)	Yes: Claims	1-13, 18-21, 24-27
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

PCT/EP2004/013435

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Claims 14-17, 22, 23, 28, 29 correspond to claims 13-16, 21, 22, 28, 29 as originally filed. These claims were not linked as to form a single general inventive concept with the other claims. To the invitation to pay the three additional search fees, the applicant did not react, therefore these claims were not searched. Consequently, no opinion can be given for claims 14-1, 22, 23, 28, 29 as no search report has been established for these claims.

**Re Item IV**

**Lack of unity of invention**

The separate groups of inventions are:

Invention 1: claims 1-13, 18-21, 24-27

Combination of dedicated dental implant or implant assembly, prosthesis and retaining screw wherein the diameter of the screw is smaller than the diameter of the anchorage part of the prosthesis. Impression coping with an anchorage part including a flat surface. Burn-out cylinder comprising a proximal end which comprises a flat surface.

Invention 1.1: claims 1-13, 18-21

Combination of dedicated dental implant or implant assembly, prosthesis and retaining screw wherein the diameter of the screw is smaller than the diameter of the anchorage part of the prosthesis.

Invention 1.2: claim 24

Impression coping with an anchorage part including a flat surface.

Invention 1.3: claims 25-27

Burn-out cylinder comprising a proximal end which comprises a flat surface.

Invention 2: claims 14-17

Dental implant replica comprising a flat-surfaced proximal end.

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

**PCT/EP2004/013435**

Invention 3:     claims 22, 23  
                  Centring screw with tapered distal section.

Invention 4:     claims 28-29  
                  Combination of an impression coping and impression coping screws  
                  wherein one or more of the impression coping screws have a flat  
                  cylindrical head or a bulbous head.

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT)  
for the following reasons:

Prior art document WO9710770 discloses a combination of dedicated implant,  
prosthesis and retaining screw (36) wherein the anchorage part of the prosthesis  
comprises a hole (18) for the retaining screw (36), said retaining screw having a neck  
diameter smaller than the hole in the anchorage part of the prosthesis (see figure 4).

The subject-matter of the independent claims related to the above identified groups of  
inventions differs from the combination known from prior art document WO9710770 by  
the following possible special technical features (STF) (Rule 13.2 PCT):

- 1.1   Claims 1 and 18: Movement of the center of the prosthesis relative to the center of  
          the of the implant allowed
- 1.2   Claim 24: Impression coping
- 1.3   Claim 25: Burn-out cylinder
  
- 2     claim 14: Dental implant replica
- 3     claim 22: Centering screw with tapered distal section
- 4     claim 28: Combination of an impression coping and one or more impression  
          coping screws having either a flat cylindrical head with a diameter equal to that of  
          the distal part of the coping or a bulbous head with a diameter which is larger than  
          that of the distal part of the coping.

The above mentioned STF solve respectively the following problems:

- 1.1   Compensating lateral misalignments between the prosthesis and the implant.
- 1.2   Reproducing the position of the implanted implant.
- 1.3   Providing building element for manufacturing the prosthesis.

- 2 Representing the position of a dental implant in a positive model.
- 3 Keeping components in place during impression process.
- 4 Providing two different alternative combinations of impression coping and impression coping screws.

The subject-matters of claims 14, 24 and 25 have in common that the proximal end has a flat surface. However impression components like impression copings or burn-out cylinders with a flat proximal end are already known (see document US4 955 811 figures 9 and 11A).

The above mentioned STF are not the same and do not correspond as they solve different problems. Consequently, no single general inventive concept can be formed between the identified inventions (Rule 13.1 PCT). The requirements of unity of invention are not fulfilled.

#### **Re Item V**

#### **Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following documents:  
D1 : WO 92/03984 A (WILJE, OSCAR) 19 March 1992 (1992-03-19)  
D2 : US 5 564 925 A (SHAMPANIER ET AL) 15 October 1996 (1996-10-15)  
D3: WO 97/10770 A (IMPLANT INNOVATIONS, INC) 27 March 1997 (1997-03-27)  
D4: US-A-4 955 811 (LAZZARA ET AL) 11 September 1990 (1990-09-11)  
D5: EP0640322 (NOBELPHARMA AB) 1 March 1995 (1995-03-01)

#### **2. INDEPENDENT CLAIM 1**

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.

- 2.1 The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document):

a combination of dedicated implant (1) or implant assembly, prosthesis (2) and retaining screw (3), wherein anchorage part of the prosthesis comprises a hole (17) for retaining screw (3), wherein the diameter of the neck of the retaining screw is smaller than the hole (17) in the anchorage part of the prosthesis (2) so as to allow, upon fixing of the prosthesis (2) to the implant (1) or implant assembly with retaining screw (3), compensation for misalignments between the center of the anchorage part of the prosthesis and the center of the implant or the implant assembly (see page 5 paragraph 2 to page 7 paragraph 1 and figures 1-3)

The subject-matter of claim 1 therefore differs from this known combination in that: the interface of said implant or implant assembly with the anchorage part of the prosthesis comprises a flat-to-flat connection allowing lateral movements of the prosthesis on the implant of about 0.4 to about 1.4 mm.

The problem to be solved by the present invention may therefore be regarded as providing compensation of lateral misalignments between the center of the anchorage part of the prosthesis and the center of the implant or implant assembly.

The solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

In document D1, the interface of the implant with the anchorage part of the prosthesis is made of a cooperation of a convex surface and a concave surface which allows an adjustment of an angular position of the prosthesis. Moreover, from D1, the person skilled in the art is aware that the configuration of this interface can be modified (see D1 page 9).

Trying to solve the above mentioned problem, the person skilled in the art would regard as a normal option to adapt a flat-to-flat configuration to the interface of the implant with the anchorage part of the prosthesis.

Moreover, the combination of a flat-to-flat connection and the existence of a play between the fixing screw and the hole of the element to be fixed has already been used in the same technical field (see document D5 column 3 lines 4-21).

In document D5, a flat gold screw is used to create a certain desirable play between a gold cylinder which is part of a prosthesis and a distance member mounted on an implant (see column 4 lines 19-24). Such predetermined play is preferably within the range of 0.05 - 0.2 mm (see column 4 lines 51-57).



The skilled person would regard as a normal measure to increase this play in order to increase the lateral movements. Therefore a play of about 0.4 to about 1.4 mm is considered as obvious.

Therefore, the person skilled in the art would consider the teaching of document D5 and combine it with the device known from D1 in order to solve the problem posed.

Consequently, the subject-matter of claim 1 does not involve an inventive step.

- 2.2 Lack of inventive step of claim 1 can be demonstrated also if document D5 is considered as the closest prior art for the subject-matter of claim 1.

The subject-matter of claim 1 differs from the combination disclosed in document D5 (see D5 column 4 lines 19-24 and column 4 lines 51-57) in that the lateral movements of the prosthesis on the implant are of **about 0.4 to about 1.4 mm**. The problem to be solved by the present invention may therefore be regarded as providing increased lateral movements.

As mentioned in the paragraph 2.1, the skilled person would consider as normal measure to chose a play falling in that range to solve the problem posed.

Therefore, the subject-matter of claim 1 does not involve an inventive step.

### 3. INDEPENDENT CLAIM 18

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 18 is not new in the sense of Article 33(2) PCT.

Document D1 discloses a retaining screw (3) **suitable** for fixing a prosthesis (2) to a dental implant (1) or implant assembly having at their interface a flat-to-flat connection or a tolerance interlock, wherein the diameter of the neck (20) of the retaining screw (3) is smaller than its threaded shaft so as to allow, upon fixing of the prosthesis (2) to the implant (1) or implant assembly with retaining screw (3), compensation for lateral misalignments between the center of the anchorage part of the prosthesis and the center of the implant or the implant assembly (see page 7 paragraph 3 and figure 2).

In claim 18, the feature consisting of *a diameter of the neck about 0.4 to 1.2 mm smaller with respect to the diameter of the hole in the anchorage part of the prosthesis* has no limiting effect on the screw self as the prosthesis does not belong to the scope of protection of claim 18.

**4. INDEPENDENT CLAIM 24**

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 24 is not new in the sense of Article 33(2) PCT.

Document D4 discloses an impression coping (150) for taking an impression of a dental implant or implant assembly comprising at its proximal end a flat surface, said impression coping comprising an anchorage part having a flat surface (see figure 9).

**5. INDEPENDENT CLAIM 25**

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 25 is not new in the sense of Article 33(2) PCT.

Document D4 discloses a burn-out cylinder (200) suitable for connection to an implant replica according to claim 13 comprising a proximal end which comprises a flat surface (see column 6 lines 29-53 and figure 11A).

**6. DEPENDENT CLAIMS 2-13, 19-21, 26, 27**

Dependent claims 2-13, 19-21, 26, 27 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:

- 6.1 The additional features of claims 2, 3, 6, 7, 10, 20 are considered to be known from document D1 (see passages of the search report).
- 6.2 The additional features of claims 26 and 27 are considered to be known from document D4 (see passages of the search report).
- 6.3 The additional features of claims 4, 5, 8, 9, 11-13, 19 and 21 are considered as obvious modifications that the skilled person would consider within the framework of his or her normal practice.

Amended claims for PCT/EP2004/013435 (clean copy)

1. A combination of dedicated dental implant or implant assembly, prosthesis and retaining screw, wherein the anchorage part (1) of the prosthesis comprises a hole (2) for the retaining screw, characterized in that the diameter of the neck (3) of the retaining screw is smaller than the hole in the anchorage part of the prosthesis and further characterized in that the interface of said implant or implant assembly with the anchorage part of prosthesis comprises a flat-to-flat connection, so as to allow, upon fixing of the prosthesis to the implant or implant assembly with retaining screw, compensation for lateral misalignments between the center of the anchorage part of the prosthesis and the center of the implant or implant assembly, by way of lateral movements of the prosthesis on the implant of about 0,4 to about 1,4 mm.
2. The combination according to claim 1, wherein the diameter of the neck (3) of the retaining screw is about 0.4 to 1.2 mm smaller with respect to the diameter of hole (2) in the anchorage part of the prosthesis.
3. The combination of claim 1 or 2, which is further characterized in that the diameter of the neck (3) of the retaining screw is smaller than its threaded shaft (15) .
4. The combination of claim 3, characterized in that there is no tolerance between the threaded shaft (15) of the retaining screw and the hole (2) in the anchorage part of the prosthesis.
5. The combination of claim 1 or 2, wherein the interface of said implant or implant assembly with the anchorage part of prosthesis is characterized by interlocking features which ensure a tolerance interlock, allowing, upon fixing of the prosthesis to the implant or implant assembly with the retaining screw, compensation for lateral misalignments between the center of the anchorage part of the prosthesis and the center of the implant

or implant assembly.

- 5      6. The combination according to any one of claims 1 to 5, wherein said anchorage part is a separate cylindrical component that can be incorporated into a prosthesis.
7. The combination according to claim 6, wherein said anchorage part is integral part of the prosthesis.
- 10      8. The combination of any one of claims 1 to 7, wherein said implant is a single structure and said flat-to-flat connection or said tolerance interlock is between the proximal surface of the fixture head (6) of said implant and the proximal surface of the anchorage part of the prosthesis.
- 15      9. The combination of any one of claims 1 to 7, wherein said implant assembly comprises an abutment and said flat-to-flat connection or said tolerance interlock is between the abutment and the anchorage part (1) of the prosthesis.
- 20      10. The combination of any one of claims 1 to 9, wherein said implant has an external surface comprising a distal part (7) which is treated to interface with bone and a proximal part (8) which is untreated, characterised in that the proximal part has a length of between 2 and 6 mm.
- 25      11. The combination of claim 1, wherein the fixture head of said implant at the interface of said implant with the prosthesis having a flat surface, further comprises in said flat surface one or more dedicated features to allow easy extraction of said implant after placement.
- 30      12. The combination of claim 1, further comprising an impression coping which comprises an anchorage part with a proximal surface, characterised in that said proximal surface is flat.

7-02-2006

Bird Goën &amp; Co

3

M3153-PCT

13. The combination of claim 1, further comprising an implant replica, characterised in that it comprises a proximal end of which the proximal surface is flat (9) for connection with the anchorage part of said prosthesis or said impression coping having an anchorage part with a proximal flat surface.

14. A dental implant replica characterised in that it comprises a flat-surfaced proximal end (9) for connection with the proximal flat surface of an anchorage part of a prosthesis or an impression coping.

15. The implant replica of claim 14, further comprising one or more flat indentations (10) on its external surface for anchoring into a plaster cast.

16. The implant replica of claim 14, further comprising a tapered distal end (11) for insertion into a resin mould.

17. The implant replica of claim 14, comprising in said flat surface, an opening to an internal threaded hole (12) for introduction of a screw, characterized in that the diameter of the opening and hole are the same size as or smaller than the diameter of the opening in the anchorage part of said prosthesis or impression coping.

18. A retaining screw for fixing a prosthesis to a dental implant or implant assembly having at their interface a flat-to-flat connection or a tolerance interlock, said retaining screw being characterized in that the diameter of its neck (3) is smaller than its threaded shaft (15) and in that the diameter of its neck (3) is about 0.4 to 1.2 mm smaller with respect to the diameter of hole in the anchorage part of the prosthesis, so as to allow, upon fixing of the prosthesis to the implant or implant assembly, compensation for lateral misalignments between the center of the anchorage part of the prosthesis and the center of the implant or implant assembly.

19. The retaining screw according to claim 18, further characterized in that it has a cylindrical head (13) with a conical opening inwards (14) to guide the screwdriver into position for screwing.
- 5 20. The retaining screw of claim 18, characterized in that the threaded shaft (15) fits into the threaded hole in the implant or implant assembly.
21. The retaining screw of claim 18, characterized in that the diameter of the threaded shaft (15) of the retaining screw is equal to the diameter of the  
10 hole (2) in the anchorage part of the prosthesis.
22. A centering screw for fixing a cylindrical component to the implant replica of claim 14 in the production of prosthesis, said centering screw having an externally tapered distal section (16) and having a threaded shaft (17)  
15 which fits into the threaded hole (12) of said implant replica.
23. The centering screw of claim 22, further characterized in that said externally tapered distal section at its widest part has the same diameter as the inner diameter of the cylindrical component so that the tapered  
20 shape ensures centering of the screw with respect to the hole in the anchorage part of said implant replica.
24. An impression coping for taking an impression of a dental implant or implant assembly comprising at its proximal end a flat surface, said  
25 impression coping comprising an anchorage part (18) having a flat surface.
25. A burn-out cylinder for connection to the implant replica of claim 14, comprising a proximal end (19) which comprises a flat surface.
- 30 26. The burn-out cylinder of claim 25, which further comprises a tapered collar (20).
27. The burn-out cylinder of claim 25, further comprising an internal shaft

comprising two cylindrical parts, wherein the diameter of proximal of said two parts is smaller than that of the distal part.

- 5 28. A combination of an impression coping and one or more impression coping screws for fixing to a dental implant or implant replica, said impression coping comprising an internal cylindrical hollow shaft and said impression coping screws comprising a threaded shaft having a diameter corresponding to the diameter of the cylindrical hollow shaft in the
- 10 impression coping, characterized in that said one or more impression coping screws can have either a flat cylindrical head with a diameter that is exactly equal to that of the distal part of the coping or a bulbous head with a diameter which larger than that of the distal part of the coping.
- 15 29. The combination according to claim 28, wherein said coping impression has a tapered external shape with a concave intrusion circumferentially along the external surface of its proximal part.

20